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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,928	01/29/2002	David Segev	01/21646	3760

7590

05/27/2005

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EXAMINER

RILEY, JEZIA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/057,928	Applicant(s) SEGEV, DAVID	
	Examiner Jezia Riley	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-93 is/are pending in the application.
- 4a) Of the above claim(s) 40-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 and 89-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-93 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/17/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of Group I and species election in the reply filed on 7/14/04 and 3/7/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1, 2, 4, 6-10, 12, 14-17, 19, 21-25, 27, 29-39, 89-93 read on elected species. After searching said elected, species, the examination of the instant application has been extended to include all possible species. Therefore Claims 1-39 and 89-93 have been examined and claims 40-87 have been withdrawn.

Drawings

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figure 1a and 1b are not formal drawings. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is vague and indefinite because it is unclear of what are the metes and bounds for the term "derivatives thereof". This term can encompass a large number of possible compounds in organic chemistry.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-39 and 89-93 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compound as shown in Figure 10 (v), does not reasonably provide enablement for compounds as broadly claimed in instant claim 1. Claim 1 is a compound comprising a backbone bearing a plurality of ligands and said ligands include at least one pair of adjacent ligands linked via a linker. And said compounds can be used in pharmaceutical composition as an active ingredient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification discloses several examples of how to prepare some specific compounds. Additionally, there is no guidance as how one of ordinary skill in art will select a specific compounds from the one as broadly claimed in

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claim 1 for example, as an active ingredient in a pharmaceutical composition. One skilled in the art would recognize that the efficacy of an oligomeric analog or mimic for these uses depends critically on its having suitable conformation and flexibility, and also of its ability to penetrate cell membranes; and it is highly unpredictable whether a given oligonucleotide or mimic structure will permit binding to the target with high specificity and affinity. The efficacy of oligo analogs as hybridizing therapeutic agents depends unpredictably on the structures of the oligos. Uhlmann et al. (Chem. Reviews, 1990, 90, pp.544-584) state that modified, nuclease-resistant oligos often have lower affinities for their target sequences than do natural DNA or RNA oligos (page 562, right col., 2nd paragraph; page 564, first full paragraph), that modified oligos may not penetrate cells as well as unmodified oligos (Page 568), and may fail to be taken up and transported into the target cells in amount capable of delivering a therapeutic benefits (page 567). In view of the breadth of the claims, which encompass an immense number of oligo mimic compounds of unknown activity; given that it is impossible to predict which of the multitude of oligo mimic structures encompassed by the claims would be able to bind successfully to a complementary nucleic acid or to protein with high affinity and specificity; and given the lack of guidance in the specification regarding how to select which of the specific oligos mimic structures encompassed by the claims could be made and used with a reasonable expectation of success, undue experimentation is required to make and use the invention as broadly claimed.

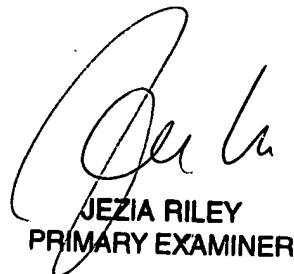
7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 571-272-0786. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thursday, May 26, 2005



JEZIA RILEY
PRIMARY EXAMINER